



Date 16/02/2012  
EMA/CHMP/SAWP/114282/2012  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 13-16 February 2012

### ***Pre-authorisation: scientific advice and protocol assistance EMA centralised procedures***

	1995 - 2011	2012	Overall total
Scientific Advice	1627	40	1667
Follow-up to Scientific Advice	400	15	415
Protocol Assistance	342	10	352
Follow-up to Protocol Assistance	162	7	169
HTA parallel advice	8	1	9
Qualification of novel methodologies	14	4	18
	<b>2553</b>	<b>77</b>	<b>2630</b>

FDA Parallel Scientific Advice	2006 - 2011	2012	Overall total
Completed	17	0	17

### ***Outcome of the February 2012 CHMP meeting in relation to scientific advice procedures***

#### **Final scientific advice procedures**

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of fatty liver and Non-Alcoholic Steatohepatitis / Nonalcoholic Fatty Liver disease (NASH/NAFLD).	x					x	x	



Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Improvement of glycemic control in type 1 and type 2 diabetes mellitus.			x				x	
Biological	Treatment of type 2 diabetes mellitus.	x					x	x	
Chemical	Treatment of type 2 diabetes mellitus.	x				x	x	x	
Chemical	Treatment of Fabry disease.				x			x	x
Biological	Treatment of retinitis pigmentosa.		x			x	x	x	
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.			x		x		x	
Chemical	Treatment of Acute Myeloid Leukemia.		x			x	x		
Biological	Treatment of steroid resistant acute Graft-versus-Host disease.		x				x	x	
Biological	Treatment of advanced Hodgkin lymphoma.				x			x	
Advanced therapy	Treatment of metastatic hormone refractory prostate cancer.			x				x	
Advanced therapy	Treatment of metastatic hormone refractory prostate cancer.	x					x		
Biological	Treatment of systemic lupus erythematosus.	x					x	x	
Chemical	Treatment of relapsed Chronic Lymphocytic Leukaemia.		x					x	x
Biological	Treatment of Behçet's Disease Uveitis.			x				x	
Biological	Treatment of sepsis induced by peritonitis.	x				x	x	x	
Advanced therapy	Treatment of pancreatic cancer.		x				x		
Biological	Treatment of non-small cell lung cancer.	x				x	x	x	
Chemical	Treatment of pancreatic cancer.		x				x	x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of new onset Giant Cell Arteritis.	x						x	
Biological	Treatment of HER2-overexpressing breast cancer and metastatic gastric cancer.			x		x		x	
Advanced therapy	Treatment of haemophilia B.	x					x		
Advanced therapy	Prevention of TRM following mismatched allogeneic HSCT.				x	x			
Biological	Treatment of sepsis with coagulopathy.	x				x	x	x	
Chemical	Reduction of major adverse cardiovascular events (MACE) in patients with high risk vascular disease.	x					x	x	
Biological	Prophylaxis of tuberculosis.	x						x	
Chemical	Oral contraception in women who elect to use folate supplementation.	x						x	
Chemical	Treatment of rheumatoid arthritis.			x				x	
Chemical	Treatment of generalised tonic-clonic seizures in epilepsy.			x				x	
Chemical	Treatment of behavioural variant frontotemporal dementia.		x				x	x	
Chemical	Treatment of multiple sclerosis.			x				x	
Chemical	Treatment of moderate to severe Alzheimer's disease.	x				x		x	
Chemical	Treatment of asthma and COPD.			x				x	
Biological/Other innovative	Treatment of severe allergic asthma.	x				x	x		
Biological	Reversal of anticoagulation effect of dabigatran.	x						x	
Chemical	Intended for the use with ultrasound imaging to improve visualization of lesion-related vascularity.	x						x	

**SA: scientific advice**  
**PA: protocol assistance**

The above-mentioned 17 Scientific Advice letters, 7 Protocol Assistance letter, 9 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 13 – 16 February 2012 CHMP meeting.

### **New requests for scientific advice procedures**

The Committee accepted 31 new Requests for which the procedure started at the SAWP meeting held on 30 – 2 February 2012. The new requests are divided as follows: 17 Initial Scientific Advice, 8 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 0 HTA parallel advice and 0 Qualification of novel methodologies.